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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,632	04/02/1999	NATHANIEL T. BECKER	GC530-2	3949

5100 7590 06/09/2003

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/285,632

Applicant(s)

BECKER ET AL.

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27, 41, 42, 46-48 and 50-77 is/are pending in the application.
- 4a) Of the above claim(s) 57 and 59-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 41, 42, 46-48, 50-56, 58, 76 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's Change of Address filed 11/25/02,
Request for Extension of Time, Amendment, and Declaration filed 04/12/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-27, 41, 42, 46-48, 50-56, 58, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,356,467.

Oshlack teaches controlled release coating composition comprising zein, water soluble plasticizer, and mixture of rate-controlling agents, including water soluble hydrophilic polymers and modified starch (columns 4-5, and 7-9). The coating is useful for coating agricultural, food, household products, and pharmaceutical, e.g., tablet core, granule, microspheres, seeds, pellets, or beads (column 7, lines 28-40).

The examiner notes that the reference briefly mentions the combination of hydrophobic acrylic polymer as a pore-former, with no further indication or explanation as to its function. However, Oshlack teaches the advantageous results in obtaining a predetermined controlled release rate, or a selected desired release rate by adding a rate-controlling agent, erosion promoting agent, and release modifying passageways forming (column 4, lines 64 through column 5, lines 1-13). Thus, it is the position of the

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examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable amount of water-soluble rate-controlling agent, erosion promoting agent, or pore-forming agent to obtain a desirable release/dissolution rate.

Oshlack teaches a pharmaceutical formulation in the form of tablets, beads, seeds, or granules that can be coated with a coating composition comprising water-soluble hydrophilic polymers (column 10, lines 45-06), modified starch (column 11, lines 12-41), and plasticizer (column 12, lines 29 through column 14, lines 1-40).

The examiner notes that the reference teaches the use of hydrophobic acrylic polymer in certain preferred embodiments. However, applicant has not provided any comparative data showing that the presence of the hydrophobic acrylic polymer would have a detrimental effect upon the desirability to obtain a useful coating composition. Hence, it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify Oshlack's coating composition with the expectation of at least similar result, because Oshlack recognizes the properties of modified starch and cellulose in coating composition useful for the same purpose desired by the applicant, *e.g.*, coating composition for cleansing agent, therapeutic active agent, fertilizing agent, or disinfecting agent.

Regarding to claim 42, Oshlack is silent as to the disclosing of enzyme. However, Oshlack teaches a cleansing agent including deodorant, surfactant, germicide, and sanitizer. Hence, it would have been *prima facie* obvious for one of the

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ordinary skill in this art to, by routine experimentation determine a suitable cleansing agent including enzyme. The reason for this modification is to obtain a stable coated composition that is useful in the pharmaceutical and cosmetic arts.

Response to Arguments

Applicant's arguments filed 04/12/03 have been fully considered but they are not persuasive.

Applicant argues that applicant believes the rejection of claim 57 under 35 CFR §112 is to be in error, and request that the rejection be withdrawn. In response to applicant's argument, according to the last Office Action dated 11/18/02, claim 57 was not rejected under 35 CFR §112. Claim 57 was withdrawn from further consideration as being drawn to a non-elected invention.

Claims 22-27, 41, 42, 46-48, 50-56, 58, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,356,467.

Applicant argues that the controlled release coating of Oshlack by definition, cannot rapidly dissolve in use because a coating could not provide "controlled release" of anything. In response to applicant's argument that the reference does not show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., rapidly dissolve coating) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant claims and specification do not disclose, mention, or require the

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invention to be a rapid dissolve coating; nor applicant claims exclude the coating to be a "control coating".

Applicant argues that all of the present claims distinguish over Oshlack since all embodiments of Oshlack require a water insoluble polymer. Applicant further alleges that Oshlack's release rates are delayed release. Contrary to the applicant's argument, applicant's claims do not exclude the coating from "controlled release", "sustained release", or "delayed release". The time release being argued in page 3 of applicant's remarks is irrelevant with respect to the scope of the claims. The language "a coating" permits any type of coatings, including the control coating disclosed by Oshlack.

Although Oshlack teaches the use of water insoluble polymer, applicant has not provide data showing detrimental effect in the present of the present of the water-insoluble polymer in such a small amount 0.1% (column 3, line 56). Oshlack recognizes the advantageous results in obtaining a predetermined controlled release rate, or a selected desire release rate by adding a rate-controlling agent, erosion promoting agent, and release modifying passageways forming (column 4, lines 64 through column 5, lines 1-13). Thus, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable amount of water-soluble rate-controlling agent, erosion promoting agent, or pore-forming agent to obtain a desirable release/dissolution rate.

Applicant argues that the examiner continues to ignore the clear fact that all of Oshlack's embodiments have a hydrophobic, insoluble, acrylic polymer as the starting material for a "controlled release" coating. In contrast, applicant does not teach or

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describe a "controlled release" coating, but rather teach that soluble coating are desired, there was no reason for applicant to provide data in the specification comparing its coating to "controlled release" coatings. Contrary to the applicant's argument, ***the examiner acknowledged the present of hydrophobic acrylic polymer taught by Oshlack*** (Office Action dated 11/18/02). Nonetheless, as discussed above, applicant's claim language does not exclude the "controlled release" coating taught by Oshlack, therefore, it was suggested that applicant provides data showing detrimental effect in the use of hydrophobic acrylic polymer in an amount of 0.1%.

The use of the transitional phrase "consisting essentially of" in applicant's generic claim 22 does not exclude the use of a small amount of hydrophobic polymer taught by Oshlack, because the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials and those that *do not materially affect the basic and novel characteristic* of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). If applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Applicant's attention is called to column 7, lines 41-50, where Oshlack teaches the advantageous results desired by the applicant (as disclosed in applicant's specification page 4, 1st paragraph), e.g., the coating formulations of Oshlack is capable of producing a ***continuous film that is smooth and***

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elegant, capable of supporting pigments and other coating additives, non-toxic, inert, and ***tack-free***.

The Declaration under 37 CFR 1.132 filed 04/12/03 has been fully considered, but is insufficient to overcome the rejection of claims 22-27, 41, 42, 46-48, 50-56, 58, 76, and 77 based upon Oshlack et al. US 5,356,467 as set forth in the last Office action because it does not provide a side by side comparison of the claimed invention and those of Oshlack to support the statement "adding hydrophobic acrylic polymer would result in loss of the rapid release". There was no data or experiment in the Declaration showing the coating containing 0.1% hydrophobic acrylic polymer in combination of water-soluble rate-controlling agent, erosion promoting agent, or pore-former that would result in loss of the rapid release. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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